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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/935,417

08/22/2001

Leon V. Rudakov

52200-8006.US01

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7590

05/22/2006

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/935,417	Applicant(s) RUDAKOV ET AL.	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 1, 2006 has been entered.

Status of Claims

Claims 1-16 have been canceled.

Claims 17-19 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17, lines 5-7, recites a coating having a first layer that provides free amine groups, a second linker layer and a third cell adhesion peptide layer wherein the linker layer is positioned between and covalently bonded to each of the first and second layers". However, the second layer is the linker layer, and thus it is not clear how the linker layer can be between the first layer and itself. It appears that Applicant intends for the second layer to be between the first layer and the third layer, i.e., the cell adhesion peptide layer, and thus will be interpreted accordingly for purposes of examination.

Claim 18 is rejected under 112, second paragraph because it is dependent on claim 17, which is vague and indefinite for the reasons set forth above.

Claim 19 recites the limitation "the amino acid sequence" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428.

Alcime et al. disclose the invention substantially as claimed. More specifically, as to claim 17, Alcime discloses an expandable support frame (i.e., stent, for example, reference 32, column 6, line 48) having first and second end portions, a porous polymer sleeve (liner, for example, reference 34, column 6, line 53-55) having inner and outer surfaces, and a coating of a cell adhesion peptide (column 13, lines 56-61) carried on and attached to at least one of the inner and outer surfaces of the polymer sleeve for enhancing endothelial cell growth on the polymer sleeve.

However, Alcime et al. do not teach that the coating has a first layer that provides free amine groups, a second linker layer, wherein the linker layer is positioned between and covalently bonded to each of the first layer and the cell adhesion peptide coating/layer. Bhatnagar however teaches this limitation.

Bhatnagar teaches that the mode of attachment of a peptide to a solid phase can be covalent linkages such as by the addition of amino acids at either the N-terminus or C-terminus to provide for binding or conjugate of the peptide to the solid phase (see col. 10, lines 37-45). Bhatnagar also teaches that the necessary domain (i.e., the peptide to be bound to the support) may include spacer arms to facilitation binding (see col. 10, lines 51-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the linkage taught by Bhatnagar to bind the Alcime et al. peptide to the solid substrate because Bhatnagar teaches that this method of attachment provides the benefit of facilitating binding of the peptide to the support. The

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amino acids at the N-terminus, or alternatively the N-terminus disclosed by Bhatnagar is considered to be the claimed first layer that provides free amine groups. The spacer arm disclosed by Bhatnagar is considered to be the claimed second linker layer. (The molecules are considered to be in a layer because they are linking the peptide coating, or layer, of the Alcime et al. peptide to a substrate.) The spacer arm is in between the peptide layer and the layer of amine groups because it is disclosed to be in the necessary domain, i.e., the peptide, (see col. 10, line 52), and also because Bhatnagar discloses that additional amino acid residues or other moieties may be added to one or the other side of this domain to facilitate coupling or the like, so long as the essential cell-binding property of the domain is not substantially inhibited (col. 8, lines 1-3).

Claim 18 is a product by process claim so no weight is given to the process limitations. The product is substantially disclosed by Alcime (see above.)

2. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, and further in view of Brown et al., 6,071,305.

Alcime et al. in view of Bhatnagar disclose the invention substantially as claimed (see above). More specifically, Alcime teaches an expandable stent for treatment of blood vessels, wherein the stent includes therapeutic drugs such as heparin, column 13, lines 56-61. However, Alcime does not teach that the cell-adhesion peptide has the amino acid sequence presented as SEQ ID NO:1. However, this limitation is suggested by the prior art as described more fully below.

Brown et al. teaches the use of therapeutic drugs such as heparin or collagen on a stent (column 2, lines 38-52, column 5, line 17 and 26).

Moreover, Bhatnagar further teaches that collagen functions as a structural protein of tissues and that it is the major fibrous element in blood vessels, see column 1, lines 50-53, and that collagen participates in physiological interactions which include formation of complexes with other macro-molecules such as fibronectin and the modulation of cell proliferation, see column 2, lines 24-31. Bhatnagar further discloses that collagen appears to cause adverse reactions within the body, and thus synthetic peptides are provided that mimic the cell binding domain of collagen, see column 3, lines 21-32. Bhatnagar teaches that the synthetic peptide has the amino acid sequence as disclosed in column 3, lines 42-43, which is the same amino acid sequence as Applicant's claimed SEQ ID NO:1.

Since both Alcime and Brown both teach the use of providing a therapeutic drug such as heparin or other drugs on a stent, and Brown further teaches that the drug may also be collagen, it would have been obvious to provide collagen as the therapeutic drug in the Alcime stent with the polymer sleeve, as would be desirable for providing the benefit of a therapeutic effect as taught by Brown.

Furthermore, it would have been obvious to provide, on the Alcime stent, the synthetic peptide disclosed by Bhatnagar, as an alternative to natural collagen, because it provides the advantage of obtaining the same therapeutic effect as natural collagen but without the adverse effects of natural collagen, as taught by Bhatnagar.

Response to Arguments

Applicant's arguments filed May 1, 2006 have been fully considered but they are not persuasive.

Applicant argues on page 6 that the references, including Bhatnagar, fail to show or suggest a coating having three layers as presently claimed. Applicant asserts that Bhatnagar instead teaches synthetic compounds attached to a porous polymer apparatus and that Bhatnagar teaches the cell attaching compound may include "noninterfering moieties or spacer arms" and not a linker layer that is covalently bonded to each of the first layer and the cell adhesion peptide layer. This argument is not persuasive because Bhatnagar teaches that the mode of attachment of a cell adhesion peptide to a solid phase may be via covalent linkages including the addition of amino acids at either the N-terminus or the C-terminus and spacer arms as discussed above.

The Office also notes that the amendments to the specification refers to page 1, line 31. However, it appears that Applicant intends to refer to page 7, line 31. Applicant should correct this in the next response.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 5/15/06
Ann Lam